

Purpose

The purpose of this document is to provide logic and reasoning to illustrate that prior life testing performed on the Xi 8mm instrument family is adequate to cover the S/Si 8mm family. This coverage allows the S/Si to be included in the Reprocessing Appendices 551620-03.

Background

Life testing on the Xi 8mm instrument family was performed according to DOP 854021 Rev. I (or higher), which includes the updated Weibull analysis. Testing performed on S/Si instruments prior to Rev. I did not include this updated analysis, meaning that the number of lives tested were fewer.

DRIVERS FOR INSTRUMENT LIFE

In life testing (and in clinical use), instrument end-of-life is gated by cable failures on instruments in both S/Si and Xi platforms. Instrument drive-cable failures can occur when any or all of the following are present:

- 1) Cable Breakage – A drive-cable breaks, typically at the wrist, and instrument axis ceases to function.
- 2) Cable Stretch – The drive cable(s) overall stretch results in cable tension becoming so slack that the instrument no longer responds intuitively.
- 3) Cable Derailment - A drive cable derails, again typically at the wrist, losing its cable tension and the instrument axis ceases to function.

Cable stretch and breakage are adversely affected by increasing tension, increasing translation and decreasing the bend radius. Cable tension is software controlled and will be discussed in detail under the “APPLIED TORQUE AND RANGE OF MOTION COMPARISON” section below. Instruments in both the S/Si and Xi platforms typically lose tension as a function of increasing number of lives due to cable stretch. This loss in tension over increasing lives has a positive effect on cable life by reduces the bending stress as it translates through the wrist geometry.

There are other factors which lead to cable wear these include:

- 1) Temperature cycling – Changes in temperature during reprocessing can cause cables to lengthen and shorten thus affecting the cable tension on the instrument.
- 2) Chemical exposure – Exposure to mildly alkaline detergents during reprocessing can affect the oxide surfaces of the cables by reducing the effective diameter of each of the individual wires within the cable construction. This can also weaken the cable and lead to stretch.

INSTRUMENT DESIGN SIMILARITIES

Instruments for the S/Si and Xi platforms are similar in many regards. The materials used in the distal portion of the S/Si 8mm instruments are identical to those used in the equivalent versions of the Xi 8mm instruments.

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There are geometric similarities between the S/Si and Xi 8mm instruments as well. The cable paths through the wrists of the instruments, and to the cable attachment points on the various joint output pulleys for yaw, grip, & pitch are designed to be identical.

Although the proximal cable routing through the back-end of the instruments differ between the S/Si and Xi, both use equivalently sized clamping pulley diameters to maintain the same bend radii and input-output gear-ratios; likewise, the idler pulleys are comparably sized so ultimately the cable-path bend radii are the same for Xi and Si.

APPLIED TORQUE AND RANGE OF MOTION COMPARISON

Cable tension is generated in the instrument by the application of torque by the system to the input disks. The input disks are mechanically coupled to the clamping pulleys where the cable is wrapped. Since the root diameter of the clamping pulleys in the S/Si and Xi instrument platforms are, by design, the same, the applied system torque limits can be directly compared.

Similarly, the range of motion for both the S/Si and Xi instruments is designed to be identical. A direct comparison of the input signal range (maximum input travel) from the requirements table in 823123 Rev. BS and 823033-40 Rev. BB, Attachment 1 shows identical values for range of motion for Pitch, Yaw, and Grip.

Justification

The following logic and reasoning demonstrates that life testing Xi 8mm is applicable to instruments on the S/Si platform:

MATERIAL COMPATIBILITY

Recent testing of S/Si instruments is archived in 1024209-01R (Bipolar), 860033-01R(Non-Energy), and 862210-04R (Monopolar). Each of these life tests was performed under DOP 854021 Rev. I or higher. The sample size and number of required lives was based on the updated Weibull analysis. This testing demonstrates that the materials used in S/Si instruments can withstand the chemistry and temperatures experienced over the intended number of lives.

EQUIVALENT REPROCESSING TEMPERATURES

There are no differences in the reprocessing temperatures between the S/Si and the Xi instrument platforms.

EQUIVALENT REPROCESSING CHEMISTRY

There are no differences in the reprocessing chemistry between the S/Si and the Xi instrument platforms.

APPLICABLE TESTING

Table 1 below lists the S/Si 8mm instruments, the corresponding Xi 8mm counterpart and the applicable testing performed. In cases where the S/Si 8mm instrument does not have an Xi counterpart, a footnote provides the justification.

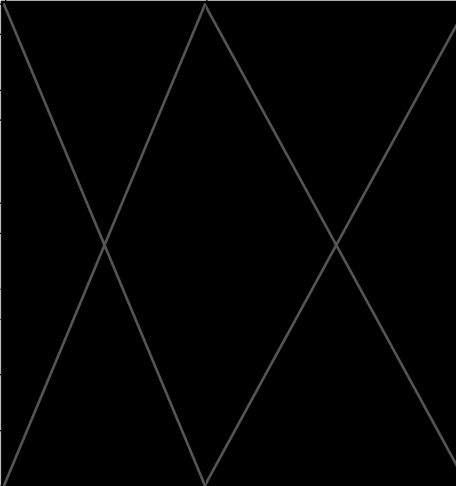
Table 1 - Applicable IS4000 Life Testing

IS3000 PN	Instrument Name	Equivalent IS4000 PN	IS4000 DHF PN	IS4000 Life test Report(s)
420001	POTTS SCISSORS	470001	1006233-060	862210-01R
420003	SMALL CLIP APPLIER	470401	1008195-060	1062218-01R
420006	LARGE NEEDLE DRIVER	470006	1005790-060	862211-01R
420007	ROUND TIP SCISSORS	470007	1008191-060	862210-03R
420033	BLACK DIAMOND MICRO FORCEPS	470033	1005791-060	862219-01R, 862219-02R
420036	DeBAKEY FORCEPS	470036	1008194-060	862221-01R
420048	LONG TIP FORCEPS	470048	1006158-060	862214-01R, 862215-01R
420049	CADIERE FORCEPS	470049	1008189-060	862221-01R
420093	PROGRASP FORCEPS	470093	1006189-060	862214-01R, 862214-02R
420110	PRECISE BIPOLAR FORCEPS	N/A	N/A	1024209-01R
420121	FINE TISSUE FORCEPS	N/A	N/A	See Note 1
420157	SNAP-FIT SCALPEL INSTRUMENT	470157	1004440-060	862217-01R
420170	ENDOPASS DELIVERY INSTRUMENT	N/A	N/A	See Note 2
420171	MICRO BIPOLAR FORCEPS	470171	1004856-060	1024209-01R, 862210-03R, 862213-01R, 862217-02R
420172	MARYLAND BIPOLAR FORCEPS	470172	1005038-060	1024209-01R, 862210-03R, 862213-01R, 862217-02R
420178	CURVED SCISSORS	N/A	N/A	See Note 1
420179	MONOPOLAR CURVED SCISSORS	470179	1004502-060	862210-01R, 862210-03R
420181	RESANO FORCEPS	470181	1006192-060	862214-01R, 862215-01R
420183	PERMANENT CAUTERY HOOK	470183	1005358-060	862217-01R, 862217-02R
420184	PERMANENT CAUTERY SPATULA	470184	1004855-060	862217-01R, 862217-02R

IS3000 PN	Instrument Name	Equivalent IS4000 PN	IS4000 DHF PN	IS4000 Life test Report(s)
420189	DOUBLE FENESTRATED GRASPER	N/A	N/A	See Note 1
420190	COBRA GRASPER	470190	1008193-060	862221-01R
420192	VALVE HOOK	N/A	N/A	See Note 1
420194	MEGA NEEDLE DRIVER	470194	1008190-060	862222-01R
420203	PERICARDIAL DISSECTOR	N/A	N/A	See Note 1
420204	ATRIAL RETRACTOR	N/A	N/A	See Note 1
420205	FENESTRATED BIPOLAR FORCEPS	470205	1005083-060	1024209-01R, 862210-03R, 862213-01R, 862217-02R
420207	TENACULUM FORCEPS	470207	1006193-060	862215-01R
420215	CARDIAC PROBE GRASPER	470215	1006195-060	862214-01R, 862215-01R
420227	PK DISSECTING FORCEPS	N/A	N/A	See Note 1
420230	LARGE CLIP APPLIER	470230	1004512-060	862218-01R
420246	ATRIAL RETRACTOR SHORT RIGHT	470246	1006227-060	862214-01R, 862215-01R
420249	DUAL BLADE RETRACTOR	470249	1006228-060	862214-01R, 862215-01R
420275	HARMONIC ACE CURVED SHEARS	N/A	N/A	See Note 2
420278	GRASPING RETRACTOR	N/A	N/A	See Note 1
420296	LARGE SUTURECUT NEEDLE DRIVER	470296	1008192-060	862212-03R
420309	MEGA SUTURECUT NEEDLE DRIVER	470309	1006155-060	862212-01R, 862212-03R
420318	SMALL GRASPING RETRACTOR	470318	1006229-060	862214-01R, 862215-01R
420327	MEDIUM-LARGE CLIP APPLIER	470327	1004503-060	862218-01R
420344	CURVED BIPOLAR DISSECTOR	470344	1005789-060	1024209-01R, 862210-03R, 862213-01R, 862217-02R

Notes:

- 1) Several S/Si 8mm instrument do not have an equivalent Xi 8mm counterpart, however, these instruments are driven with torques lower than those present in the IS4000 8mm Large Clip Applier. The table below compares the highest value among Yaw, Grip Open, or Grip Closed torques present in 823123 Rev. BS to that of the IS4000 8mm Large Clip Applier.

IS3000 PN	Instrument Name	Max Torque (Yaw, Grip Open, Grip Closed) (Nm)	IS4000 Large Clip Applier Max Grip Closed Torque (Nm)
420121	FINE TISSUE FORCEPS		
420170	ENDOPASS DELIVERY INSTRUMENT		
420178	CURVED SCISSORS		
420189	DOUBLE FENESTRATED GRASPER		
420192	VALVE HOOK		
420203	PERICARDIAL DISSECTOR		
420204	ATRIAL RETRACTOR		
420227	PK DISSECTING FORCEPS		
420275	HARMONIC ACE CURVED SHEARS		
420278	GRASPING RETRACTOR		

- 2) The two remaining instrument in the S/Si 8 mm family which were not discussed in this justification are the Endopass Delivery Instrument, PN 420170, and the Harmonic Ace Curved Shears PN 420275. These instruments are simple and robust in design and do not have cables and are therefore less likely to fail due to the increased number of reprocessing cycles.

In summary, because of the similarities in design, materials, reprocessing temperatures, reprocessing chemistry, input drive torque and range of motion, the testing performed on the Xi 8mm instrument family is adequate to cover the S/Si 8mm family. This coverage allows the S/Si to be included in the Reprocessing Appendices 551620-03.